K132416

MAY 2 8 2014

009_510(k) summary

21CFR807.92 / special 510(k)

Name of the legally marketed (unmodified) device

Proprietary name:	RehaStim 2;
	RehaMove 2 (RehaStim 2 with movement exerciser)
510(k):	K112844
Device Class:	class 2 device
Classification:	Neurology

Submitter's / owner's name, address, Telephone number, a contact person, and the date the summary was prepared:

510k Submitter:	Hasomed GmbH
Contact person:	Matthias Weber
Address:	Paul-Ecke-Strasse 1
	39114 Magdeburg
	Germany
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Prepared on July 02, 2013

Name of device, including the trade or proprietary name if applicable, the common or usual name, and the classification name :

Proprietary name:	RehaStim 2 ErigoPro (FES)
Common Name:	Powered Muscle Stimulator
Classification Name:	Powered Muscle Stimulator

Identification of the legally marketed device to which the submitter claims equivalence:

Manufacturer:	HASOMED GmbH
Product:	RehaStim 2; RehaMove 2
K-number:	K112844
Class:	class 2 device
Product Code:	GZI

A description of the device that is the subject of the premarket notification submission:

The Erigo is an early rehabilitation robotic device consisting of a verticalization table and an integrated leg movement mechanism. By moving the patient's legs, cyclic leg loading is applied to the lower limbs of the patient during early verticalization. The Erigo is controlled via a PC.

The ErigoBasic offers all basic functionalities to perform early and safe patient mobilization. With the ErigoPro, patient stimulation is additionally enhanced by the synchronized FES.

The FES – stimulation controller RehaStim 2 generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. A connection cable enables the RehaStim 2 to receive the stimulation parameters from the ErigoPro control system. The electrode lead wires are used to connect ErigoPro-FES-Socket/RehaStim2 output and electrodes on skin. Every connected lead wire should connect to two electrodes (1 channel) for ErigoPro and 2x 4 channels for RehaStim2, respectively.

Statement of the intended use of the device:

Both the RehaStim 2 and the ErigoPro (FES) are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Technological Characteristics

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RehaStim 2 / ErigoPro (FES)	RehaStim 2 / RehaMove 2
Power Source	AC: **ErigoPro:** Total System: 110-240V 800VA Includes RehaStim2 power supply: cincon tr30m ac-cording to EN60601-1	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,

	RehaStim2 (only): AC: power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	
Controller	Uses custom processor, running LinuxOS ,running custom software ErigoPro: RehaStim2 is controlled by ErigoPro Control Panel	Uses custom processor, running LinuxOS ,running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses	0-130mA charge balanced stimulator with rectangular impulses
patient part	Type: BF	Type: BF
movement exerciser	The Erigo is an early rehabilitation robotic device consisting of a verticalization table and an integrated leg movement mechanism.	RehaMove 2: Uses motor to create flywheel effect with reduced weight and space
Passive cycling	ErigoPro: By moving the patient's legs, cyclic leg loading is applied to the lower limbs of the patient during early verticalization.	RehaMove 2: Utilizes motor to provide assistance during passive cycling
FES control	Synchronization of movement angle and stimulation control	Synchronization of movement angle and stimulation control

Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent function-nality was implemented in ErigoPro (FES).
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables
Output characteristic measurement of new device	The ErigoPro (FES) / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the ErigoPro (FES) and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using gradual verticalization, robotic leg movement, and cyclic leg loading has been extensively demonstrated in particular by the ongoing clinical use of the device without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and ErigoPro (FES) and many clinical applications.

In conclusion, HASOMED´s clinical and non- clinical testing have demonstrated that the RehaStim 2 and ErigoPro (FES) are as safe and effective as the predicate device.

Product code: GZI

Common Name: Powered Muscle Stimulator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

HASOMED GmbH
Matthias Weber
Managing Director
Paui-Ecke-Strasse 1
39114 Magdeburg
Germany

Re: K132416
Trade Name: ErigoPro
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI, BXB, INQ
Dated: April 15, 2014
Received: April 21, 2014

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132416

Device Name
ErigoPro

Indications for Use *(Describe)*
The ErigoPro is intended for medical purposes such as to increase tolerance to an upright or standing position in patients with circulatory, neurological, or musculoskeletal conditions.

ErigoPro is also used for:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy / redevelop muscles
3. Increasing local blood circulation
4. Maintaining or increasing joint range of motion

The ErigoPro is for prescription use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.28 17:08:42 -04'00'

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